MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

NOTICE OF PROPOSED POLICY

Public Act 280 of 1939, as amended, and consultation guidelines for Medicaid policy provide an opportunity to review proposed changes in Medicaid policies and procedures.

Please review the policy summary and the attached materials that describe the specific changes being proposed. Let us know why you support the change or oppose the change.

Submit your comments to the analyst by the due date specified. Your comments must be received by the due date to be considered for the final policy bulletin.

Thank you for participating in the consultation process.

Director, Program Policy Division
Bureau of Policy and Federal Affairs
Policy and Legal Affairs Administration

Project Number:	0233-P	**Comments Due:**	2/20/03	**Proposed Effective Date:**	4/1/03

Mail Comments to: James Kenyon
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Precertification, Pharmaceutical and Beneficiary Services Bureau
Division of Pharmacy
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Policy Subject: Pharmacy Chapter III Updates

Affected Programs: Medicaid Fee for Service, SMP, MOMS, RAP, and CSHCS Fee for Service

Distribution: Pharmacy

Policy Summary:
The attached Pharmacy Manual pages contain changes being implemented 4/1/2003. The changes will affect the publication of the MDCH Michigan Pharmaceutical Product List (MPPL) and impact how Fee For Service pharmacy providers bill claims for H 2 Antagonists and Proton Pump Inhibitors (PPIs).

Printed copies of the MPPL will no longer be distributed, but an electronic NDC version will be posted on the website **www.michigan.fhsc.com**. Maximum Allowable Cost (MAC) prices will not be listed in the MPPL, but on a separate area on the above website. A new form will be available on the web for manufacturers to notify MDCH of new outpatient drugs. These changes are necessary to accommodate the new pharmacy point of sale platform.

The "Anti-Ulcer Drug Policy" is being renamed the "H 2 Antagonists and Proton Pump Inhibitor Policy" and prior authorization will be required for high dose use of these drugs beyond a 102-day supply. Only one 102-day high dose use per year will be allowed without p.a.

Proposed Policy Draft

Michigan Department of Community Health
Medical Services Administration

Distribution: Pharmacy

Issued: xxxxx-xx

Subject: Pharmacy Chapter III Updates

Effective: April 1, 2003 (Proposed)

Programs Affected: Medicaid Fee for Service, SMP, MOMS, RAP, and CSHCS Fee for Service

The attached Pharmacy Manual pages contain information about changes being implemented 4/1/2003 by the Michigan Department of Community Health (MDCH). The changes will affect the publication of the MDCH Michigan Pharmaceutical Product List (MPPL) and impact how Fee for Service pharmacy providers bill claims for H 2 Antagonists and Proton Pump Inhibitors (PPIs).

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For complete information on pharmacy billing and required fields, refer to your First Health's Pharmacy Claims Processing System for Michigan Medicaid manual, the FHSC web site [www.michigan.fhsc.com], or call the FHSC Technical Call Line number 1-877-624-5204.

The ***Michigan Pharmaceutical Product List (MPPL)*** identifies the pharmaceutical products that are covered ***for Medicaid, CSHCS, MOMS, RAP, and SMP*** programs. The MPPL is a general list of available pharmaceutical products for which coverage may vary by program. Individual beneficiary coverage may vary due to age, gender, or medical condition.

Effective April 1, 2003 MDCH will no longer publish on paper or microfiche the following:

- The MPPL
- Coverage parameters, such as,
  - Special coverages or restrictions for various beneficiary populations
  - Special billing criteria
  - Age restrictions
  - Prior Authorization requirements
- A list of rebate participating labelers
- MAC price file

Effective April 1, 2003, the following information will be posted to the website www.michigan.fhsc.com

- The MPPL as a list of covered NDCs with product descriptives.

  This list will be updated on the website as changes are made. The effective date of the coverage change and the date the list was last updated will be posted.

- Michigan MAC prices

  This list will include the effective date of the price and will be posted to the DCH website, along with the date the MAC file was last updated.

- A link to the list of rebate participating labelers.

  The list of rebate participating labelers will be available through a link from the website www.michigan.fhsc.com to the CMS website http://cms.hhs.gov/medicaid/drugs/drug7.asp

Coverage in relation to the beneficiary or pharmacy claim will be provided at the point of pharmacy claim adjudication.

MANUFACTURER NOTIFICATION OF NEW OUTPATIENT DRUGS

A manufacturer may advise the Department of a new product through the Notification of New Outpatient Drug form.

The Notification of New Outpatient Drug form is posted at www.michigan.fhsc.com. The completed form may be mailed to:

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
Notification of New Outpatient Drug Form
PO Box 30479
Lansing, Michigan 48909-7979

ADDITIONAL DOCUMENTATION

Depending on the specific drug being prescribed, additional medical documentation may be required. Provided below is the additional documentation required for the most common categories.

Brand Override

- Documentation of the therapeutic trial and failure reasons of the generic

Medication for Erectile Dysfunction

- Documentation of all other diagnoses and medication prescribed
- Medical history and results of physical examination
- Results of laboratory testing for testosterone, glucose, leutenizing hormone, follicle stimulating hormone, thrytropin if underlying cause points to testicular atrophy, hypothyroidism, etc.
- Results of testing (e.g., electrodiagnosis or nocturnal penile tumescence test) as indicated by the medical history and physical examination findings
- Summary of attempts to treat the discovered underlying causes, substitution of pharmaceuticals to treat hypertension, depression, from those agents suspected to have caused the dysfunction

Weight Loss Medications

- Current medical status, including nutritional or dietetic assessment
- Current therapy for all medical conditions, including obesity
- Documentation of specific treatments, including medications
- Current accurate BMI, height, and weight measurements
- Confirmation that there are no medical contraindications to reversible lipase inhibitor use, no malabsorption syndromes, cholestasis, pregnancy and/or lactation
- Details of previous weight loss attempts and clinical reason for failure (at least two failed attempts are required)

PRIOR AUTHORIZATION DENIALS

A prior authorization will be denied if:

- the medical necessity is not established,
- alternative medications are not ruled out,
- evidence-based research and compendia does not support,
- it is contraindicated, inappropriate standard of care,
- it does not fall within MDCH clinical review criteria, and/or
- documentation required was not provided.

ENTERAL FORMULA

Enteral formulas require prior authorization, and coverage is extended to only those enteral formulas with a unique nutritional composition from which nutrients are not obtainable from food and represent an integral part of treatment of the specified diagnosis/condition.

Prior Authorization Criteria

Authorization is based on a case-by-case review including, but not limited to, factors such as:

- Medical conditions requiring intake of a unique nutrient or ratio of specific nutrients to address increased or restricted medical requirements for these nutrients, when comparable levels cannot be obtained from regular foods and beverages
- Nutrient malabsorption associated with a specific diagnosed disease
- Supplementation to regular diet or meal replacement is only considered if there is failure to thrive when the beneficiary's weight-to-height ratio has fallen below the 5th percentile on growth grids (under the age of 21)
- Mechanical or physiological conditions precluding normal dietary intake (e.g., obstruction of the throat or esophagus)
- Temporary medical complications (e.g., nausea due to chemotherapy, post-operative healing complications) necessitating a short-term (less than two months) use of enteral formula.

Non-Covered Products

The program does **NOT** cover products, nor are exceptions made for,:

- Standard infant/toddler formulas
- Weight loss products or 'lite' products
- Puddings/Bars
- Liquid thickeners
- Regular and Special Dietetic foods
- Sports drinks

Products are **NOT** covered for the following reasons or conditions:

- Regular and special dietetic foods or formulas that represent only a liquid form of food
- Refusal to eat or poor eating behavior
- Loss of appetite
- Non-compliance with specialized diet
- As a convenience issue or inability to prepare meals
- Food preferences
- Eating disorders from such conditions as Alzheimer's, Developmental Disability, Bulimia, Anorexia

For high dose use greater than a 102-day supply in a 365-day period, prior authorization is required for H 2 Antagonists and Proton Pump Inhibitors (PPIs). The MDCH definition of high dose use is posted at www.michigan.fhsc.com. Non-preferred H 2 Antagonists or PPIs require prior authorization for both high and low dose use.

The following information is required for prior authorization determination:

- Diagnosis
- Drug and dose for which prior authorization is requested
- Date and results of GI testing
- All alternative H 2 Antagonists and PPIs tried, including dose and duration
- Other prescribed medications relating to this diagnosis
- Reason patient cannot endure testing
- Health education or other counseling employed for this condition

Prescribers or prescriber designees may request prior authorization for high dose therapy over the 102 days through the PBM Clinical Call Center. The Clinical Call Center phone number is 1-877-864-9014. H 2 Antagonists and PPIs are not considered therapeutic duplicates to Pepsin Inhibitors (i.e., Sucralfate). H 2 Antagonists and PPIs are considered therapeutic duplicates and will be denied at point of sale.

Compliance with the H 2 Antagonists and PPI Policy is monitored with Point of Sale (POS) and post-payment review.

DAYS SUPPLY

Prescription quantities are limited to the units specified by the prescriber. The Program will cover up to a 34-day supply for acute medications, and up to a 100-day supply for maintenance medications.

The pharmacy must submit accurate days supply information. Submitting incorrect days supply information can cause false ProDUR messages and claim denials. It could also result in a pharmacy being targeted for a post-payment audit.

TIMELY FILING LIMITS

The timely filing limit is 180 days from the date of service (DOS) for all original claims, reversals, and rebilled claims. An exception for TPL delay, retroactive beneficiary eligibility, MHP retroactive disenrollment or claim errors identified by MDCH may be requested.

ACUTE & MAINTENANCE SUPPLIES

Providers must bill and dispense as follows:

For acute illness:

- The amount dispensed must be limited to the quantity required for the desired therapy during that episode of illness or up to a 34-day supply.

For chronic illness:

- Maintenance drugs must be dispensed in quantities to achieve optimum therapy and economy of dispensing, or up to a 100-day supply.
- If a prescription for a product on the maintenance list is for more than a month's supply and less than a 100-day supply, only one dispensing fee is allowed.
- A pharmacy will receive a maximum of one dispensing fee per prescription for the same drug entity per month.
- A maximum of thirteen (13) dispensing fees will be paid for the same drug dispensed to the same beneficiary within a 365-day billing period.

The PBM's First Health's Pharmacy Claims Processing System for Michigan Medicaid provides a list of maintenance medications. This list DOES NOT exclude medications from other standard therapeutic class codes from being supplied in maintenance quantities. Prior authorization is necessary when a maintenance quantity of other medications is required for specific beneficiaries.

REFILLS

Refills must conform to current State and Federal statutes, rules, regulations, and policies.

RETURNED TO STOCK PRESCRIPTIONS

The Program does NOT reimburse for prescriptions filled but not dispensed to the beneficiary. For prescriptions returned to stock/not picked up prescriptions, pharmacies must claim adjust or reverse the claim for any payments received, including the dispensing fee. The pharmacy should reverse claims in a timely manner. However, Department policy allows claim adjustments or reversals to be submitted up to six months after the original date of service. For example, if the Program beneficiary does not pick up a prescription from the pharmacy within 14 calendar days from the date the prescription claim was submitted by the pharmacy, the prescription claim should be reversed on the 15th calendar day or, at a minimum, by the 180th day. For audit purposes, a record of processed reversals must be retained by the pharmacy for six (6) years.

Discounted Average Wholesale Price

The Program's discounted average wholesale price is as follows:

Pharmacy Group	Discount Used for Payment
Pharmacies with 1-4 stores	AWP minus 13.5 %
Pharmacies with 5 or more stores	AWP minus 15.1 %
Pharmacies with no retail customers servi ng LTC beneficiaries	AWP minus 15.1 %

Maximum Allowable Cost (MAC)

MAC reimbursement levels are established by the MDCH and are generally applied to multi-source brand and generic products. However, MAC reimbursement may also be applied to single source drugs. The specific pharmaceutical product MAC reimbursement level is at www.michigan.fhsc.com. All new MACs on existing products, or decreases on MACs, will be posted 30 days prior to the effective date.

Concerns regarding MAC reimbursement should be mailed or faxed to the address or fax number listed below. Information necessary for a departmental review of a MAC price should be provided and must include the following:

- Drug name and NDC requested for review.
- Reason for requested review (availability, price, or other).
- Documentation that the MAC is below cost, or the product is not available on the market (invoice(s) to support a request for change).
- Supporting claim documentation with date of service which can be used to identify the difference between reimbursement and actual cost.
- Company name, address, contact person, and phone number.

Send request for MAC review to:

Michigan Department of Community Health
Pharmacy MAC Pricing
P.O. Box 30479
Lansing, Michigan 48909-7979

Fax: 517-241-7813

MAC Overrides

Specific brand products have a MAC reimbursement level. To receive payment above the MAC reimbursement level, prior authorization is required.

DISPENSING FEES

Dispensing Fee is defined as the fee charged for filling a prescription and all related services performed by a pharmacy. The Program's dispensing fee is published in the MPPL.

Retail Price Exception (RTL)

Selected supplies are not paid a dispensing fee. Supplies indicated with an RTL in the MPPL are paid the lower of Retail Price or Retail-Based MAC price.

State Medical Program

The State Medical Program (SMP) dispensing fee is 85% of the fee paid under Michigan Medicaid.

Compounded and Re-Packaged Unit Dose

Compounded and Pharmacy Re-Packaged Unit Dose prescriptions are paid dispensing fees higher than the standard fee.